(ii) a second antibody which is capable of specifically binding to a second binding site on the antigen, wherein the second antibody is free,

thereby forming, when the antigen is present in the sample, an agglutinate comprising the first antibody, the antigen, and the second antibody; followed by

(b) optically measuring the amount of the agglutinate formed in (a),

wherein the antigen is apoprotein B, HbA_1C, serum amyloid A protein, or thrombin-antithrombin III complex.

21. (Twice Amended) An agglutination immunoassay for detecting an antigen in a sample, comprising:

(a) sequentially contacting the sample with

(i) a first antibody which is capable of specifically binding to a first binding site on the antigen, wherein the first antibody is free, and then

(ii) a second antibody which is capable of specifically binding to a second binding site on the antigen, wherein the second antibody is immobilized on an insoluble carrier,

thereby forming, when the antigen is present in the sample, an agglutinate comprising the first antibody, the antigen, and the second antibody; followed by

(b) optically measuring the amount of the agglutinate formed in (a),

wherein the antigen is apoprotein B, HbA_1C, serum amyloid A protein, or thrombin-antithrombin III complex.--

Please add the following claims.

--35. (New) The immunoassay of Claim 7, wherein the antigen is apoprotein B.

36. (New) The immunoassay of Claim 7, wherein the antigen is HbA_1C.

37. (New) The immunoassay of Claim 7, wherein the antigen is serum amyloid A protein.

38. (New) The immunoassay of Claim 7, wherein the antigen is thrombin-antithrombin III complex.

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39. (New) The immunoassay of Claim 21, wherein the antigen is apoprotein B.

40. (New) The immunoassay of Claim 21, wherein the antigen is HbA_1C.

41. (New) The immunoassay of Claim 21, wherein the antigen is serum amyloid A protein.

42. (New) The immunoassay of Claim 21, wherein the antigen is thrombin-antithrombin III complex.--

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REMARKS

Claims 7-42 are pending.

The present invention relates to an immunoassay for detecting an antigen in a sample. An important feature of the present method is that two antibodies are used to bind the antigen, and each antibody is contacted with the sample sequentially to form an agglutinate comprising the antigen and the two antibodies (see (i) and (ii) in Claims 7 and 21). Another important feature is that the antigen is apoprotein B, HbA_1C, serum amyloid A protein, or thrombin-antithrombin III complex.

The present inventors have discovered that this two-step antibody binding reaction provides a assay method having high sensitivity and low cost.

The rejections of the claims under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) over Strahilevitz (U.S. Patent No. 4,375,414) are respectfully traversed. This reference fails to disclose or suggest the claimed immunoassay method.